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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,142	10/09/2003	J. Michael Ramstack	000166.0073-US02	6453

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COVINGTON & BURLING, LLP  
ATTN: PATENT DOCKETING  
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WASHINGTON, DC 20004-2401

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/681,142

Applicant(s)

RAMSTACK ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 11, 13, 17, 19-21 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al. WO 97/44039.

Francois teaches an aqueous suspension formulation comprising particles of 9-hydroxyrisperidone dispersed or suspended in a pharmaceutically acceptable carrier such as water (page 4, lines 21-30; and page 5, lines 34-37). The aqueous suspension further comprises a suspending agent and a wetting agent, such as sodium carboxymethyl cellulose (page 6, lines 1-17). The formulation is suitable for parenteral administration through fine needle ranging from 21-22 gauge (page 7, lines 1-5; and examples). Francois does not teach mixing the ingredients in the claimed order (see page 7, lines 19-29). However, selection of any order of performing process steps is

*prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946); and *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). See also *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). Accordingly, it would have been obvious to one of ordinary skill in the art to, by routine experimentation modify the order of mixing the ingredients to obtain the claimed invention, because Francois teaches the use of the same ingredients for the same purpose, namely, an efficient, well-tolerated injectable formulation of 9-hydroxyrisperidone, suitable for fine needle having diameter ranges from 21-22 gauge.

It is noted that Francois does not teach the viscosity of the suspending agent. However, it is the position of the examiner that the suspending agent taught by Francois would have the claimed viscosity, because Francois teaches the use of the same suspending agent, *e.g.*, sodium carboxymethyl cellulose, to obtain the same composition, *e.g.*, an aqueous suspension suitable for injection through a needle into a host.

Claims 10, 12, 18, 22-28, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al. WO 97/44039, in view of Ramstack et al. WO 95/13799.

Francois is relied upon for the reason stated above. Francois does not teach binder in the particle.

Ramstack teaches a microparticles formulation suitable for parenteral administration comprising polymeric matrix including poly(D,L-lactic-co-glycolic acid)

having a molar ratio from about 85:15 to about 50:50 (pages 15-16). The microparticles further comprises risperidone as active agent (page 30, lines 16-20; and examples). Thus, it would have been obvious to one of ordinary skill in the art to modify the formulation of Francois using the microparticles of risperidone in view of the teaching of Ramstack, because Ramstack teaches a biodegradable system, an injectable system that prevents the loss of dose during treatment, because Ramstack teaches microparticles for controlled/sustained release of risperidone, because Ramstack teaches dry microparticles of risperidone are suspended in an acceptable pharmaceutical liquid vehicle prior to administration to a patient (page 29, lines 27-31), and because Francois teaches the desirability of obtaining an efficient, well-tolerated, sustained or delayed release injectable composition of a 9-hydroxyrisperidone (page 3, lines 23-26).

Claims 8, 9, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al. WO 97/44039, in view of Ramstack et al. WO 95/13799.

Francois is relied upon for the reasons stated above. Francois does not explicitly teach mixing the ingredients in a syringe.

Ramstack teaches microparticles were syringe loaded and resuspended in the syringe with an injection vehicle. The suspension was reconstituted with WFI prior to injection (page 38, lines 4-9). Thus, it would have been obvious to one of ordinary skill in the art to use the syringe in view of the teaching of Ramstack to mix the ingredients

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taught by Francois, because Ramstack teaches a known method for mixing or reconstitute active agents with an injectable vehicle prior to administration to a patient.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al. WO 97/44039, in view of Okada et al. US 5,631,021.

Francois is relied upon for the reasons stated above. Francois does not explicitly teach changing the temperature of the suspension.

Okada teaches procedures for increasing the viscosity include a heat treatment, cooling to a low temperature, freezing, changing pH, or adding carboxymethyl cellulose (column 6, lines 16-24). Thus, it would have been obvious to one of ordinary skill in the art to change the temperature of the suspension to obtain a desirable injectable formulation in view of the teaching of Okada, because Okada teaches changing temperature to obtain a desirable viscosity is well known in the art, and because Okada teaches a known equivalent of changing the temperature and adding carboxymethyl cellulose.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wallace et al., Muller et al., Hubbard, Chandrashekar et al., and Sawhney are cited as of interest for the teachings of injectable formulations comprising lubricant/wetting agent such as carboxymethyl cellulose.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran  
Primary Examiner  
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